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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/622,524	07/18/2003	Raymond A. Hui	RDI 01072CIP US	4118
23690	7590	06/24/2005	EXAMINER	
Roche Diagnostics Corporation 9115 Hague Road PO Box 50457 Indianapolis, IN 46250-0457			CEPERLEY, MARY	
			ART UNIT	PAPER NUMBER
			1641	

DATE MAILED: 06/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/622,524	HUI ET AL.	
	Examiner	Art Unit	
	Mary (Molly) E. Ceperley	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 17 March 2005.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-3,5-7,10,11,13,14,16-33 and 36 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1-3,5-7,10,11,13,14,16-33 and 36 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>1/13/05</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ |

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1) Serial numbers are missing from the text on at least pages 34 and 35. Correction is required.

Applicants should thoroughly check the specification for the possibility of other missing data.

2) Although specific claims are cited in the rejections below, these rejections are also applicable to all other claims in which the noted problems/language occur.

3) The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4) The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5) Claims 10, 11, 13 and 14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Applicants have not established that the cell lines and monoclonal antibodies designated in claims 10-14 are accessible to the public in accordance with the requirements of MPEP 2404-2411.

6) Claims 1-3, 5-7, 10, 11, 13, 14, 16-33 and 36 are pending and are examined on the merits in this Office action.

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7) Claims 33 and 36 are again rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for the reason stated in paragraph **5)a)** of the November 04, 2005 Office action.

Claims 33 and 36 are indefinite and incomplete for the reason that they fail to define how the "complex" formed by the antibody and the analyte is to be detected. Presumably the use of a tracer or labeled secondary antibody would be required to practice the methods. As the claims are presently written, it is unclear what is meant to be encompassed by the term "a label which is detectable upon binding of the antibody to the analyte". A free "label", for example an electrochemiluminescent compound in solution, would be expected to be "detectable" independent of whether or not "binding of the antibody to the analyte" occurs.

8) The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9) Claims 1-3, 5-7, 16-33 and 36 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification contains no description of the *subset* of compounds in which "L" contains a "proviso" and is defined as "comprises 1-15 carbon atoms and 0-6 heteroatoms, with the proviso that L is bound to the ring carbon atom via -CH₂- or CH₂O-" (see claim 1).

10) Claims 10, 11, 13, 14, 16-28, 33 and 36 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 17, 18, 31 and

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42-44 of copending Application No. 10/087,469 for the reason stated in paragraph **10**) of the November 04, 2004 Office action. Applicants state that in the event any pending claims are still in conflict at the time of patenting of either of applications 10/622,524 and 10/087,469 a terminal disclaimer will be filed as appropriate (March 17, 2005 Remarks, page 4).

11) Claims 10, 11, 13, 14 and 16-28 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 8 and 9 of copending Application No. 10/622,254 for the reason stated in paragraph **11**) of the November 04, 2004 Office action. Applicants state that in the event any pending claims are still in conflict at the time of patenting of either of applications 10/622,524 and 10/622,254 a terminal disclaimer will be filed as appropriate (March 17, 2005 Remarks, page 5).

12) The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13) Claims 1-3, 6, (activated haptens, tracers and immunogens) 11, 14, 16-25 (antibodies), 26-28 (antibody-containing kits), 29, 32 (production of antibodies), 33 and 36 (immunoassays) are rejected under 35 U.S.C. 103 as being obvious over each of Gross (US 3,996,344), Soares (US 4,016,146), Buechler et al (US 5,470,997), Huber et al (US 5,976,812), Heiman et al (US 5,262,333), Hu et al (US 5,135,863), Byrnes et al (US 4,868,132) or Schneider et al (US 3,878,187).

Each of the references describes methamphetamine derivatives in which the phenyl ring is substituted at the *para* position with an activated linker moiety. The linker moiety can be reacted with an immunogenic carrier or label to form the corresponding *para*-substituted methamphetamine immunogen

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(useful for developing antibodies) or detectably labeled methamphetamine derivative (tracer). The compounds of the references differ from those of the instant claims in that at least one moiety on the nitrogen atom of the compounds of the instant claims is an alkyl group of from "2-6 carbon atoms" while at least one moiety on the nitrogen of the prior art is 1-carbon atom in length. The *para*- substituted activated haptens, immunogens and tracers of the instant claims wherein the nitrogen is ethyl (through hexyl)-substituted are rendered obvious by the structurally related methyl homologues of the prior art. Absent evidence to the contrary, the claimed compounds would be expected to have very similar properties to the compounds of the prior art. See MPEP 2144.09 and 2144.08, paragraph II.A.4C. Given the structural similarities of the haptens of the instant invention and those of the prior art, the antibodies of the prior art would be expected to inherently have the same specificity for MDEA as the antibodies of the instant claims. See:

- i)* Gross: col. 3, line 10 – col. 4, line 5; col. 6, formula (5); col. 7, lines 47-48; Examples 1c. and 1d.; Example 2; claims 1, 5, 6 and 9;
- ii)* Soares: formula (5); col. 15, lines 9-13; claim 1;
- iii)* Buechler et al: Fig. 1, Example 15 ; col. 2, lines 40-42 ; col. 6, line 1 – col. 8, line 31; Examples 2, 4-8 and 10;
- iv)* Huber et al: Fig. 2, structures 15 – 17; col. 2, line 40 ; col. 3, line 50; claims 1-22;
- v)* Heiman et al: Structures 7, 8, 12 and 13 ; col. 21, lines 13-26;
- vi)* Hu et al: claim 1; col. 32, 9. ;
- vii)* Byrnes et al : FIGS. 2-B, 7, 9-A and 9-D ;
- viii)* Schneider et al : EXAMPLES II and III ; col. 12, lines 18-26.

14) Claims 1-3, 5-7, 22-25, 29-33 and 36 are rejected under 35 U.S.C. 102(b) as being anticipated by Huber et al (US 5,976,812).

Huber et al describes *para*-derivatized amphetamine haptens wherein the linker contains carbon atoms and optionally heteroatoms and is attached directly to the benzene ring; these activated haptens

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are useful in preparing the corresponding amphetamine immunogens, antibodies and tracers and anticipate the corresponding immunogens, tracers, antibodies and their method of use in an immunoassay of the instant claims wherein "L comprises 1-15 carbon atoms and 0-6 heteroatoms". See Huber et al: structures 13, 14, and 16 – 18. Instant claims 7 and 25 contain the added limitation that "R¹" is ethyl and "R²" is methyl, i.e. the terminal amine group is -N(Et)Me . Huber et al specifically describe this compound limitation at col. 2, lines 32-47 wherein "R₄" and "R₅" can be -CH₃ (methyl) or -C₂H₅ (ethyl), i.e. the terminal amine group is -N(Et)Me. Therefore Huber et al anticipates the instant claims.

At page 7 of the March 17, 2005 Remarks applicants argue that the Huber et al compounds are "all maleimide derivatives" and therefore cannot anticipate the compounds of the instant invention. However, this argument is unpersuasive for the reason that the maleimide moiety of Huber et al corresponds directly to the "Q" moiety of instant claim 1 defined as a "leaving group"

15) Claims 10, 13 and 16-28 are rejected under 35 U.S.C. 102/103(a) as being unpatentable over Huber et al (US 5,976,812).

Huber et al is applied for the reason stated in paragraph **14)** above.

In the absence of evidence to the contrary, the antibodies and cell lines (Huber et al, col. 5, lines 60-14) of the prior art are considered to have the same characteristics recited for the cell lines and antibodies of instant claims 10, 13 and 16-21. For product by process antibody claims 22-28, see MPEP 2113.

16) Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary (Molly) E. Ceperley whose telephone number is (571) 272-0813. The examiner can normally be reached from 8 a.m. to 4:30 p.m.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le, can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

June 21, 2005

Mary E. Ceperley
Mary (Molly) E. Ceperley
Primary Examiner
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